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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,067	11/05/2008	Paul Vermeij	I-2004.001 US	1685

31846 7590 03/23/2011  
Intervet/Schering-Plough Animal Health  
Patent Dept. K-6-1, 1990  
2000 Galloping Hill Road  
Kenilworth, NJ 07033-0530

EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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03/23/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ahpatentsus@merck.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,067	<b>Applicant(s)</b> VERMEIJ, PAUL	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-13,25-29,31-36 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31,32,34,35,40,41 is/are allowed.
- 6) ☒ Claim(s) 10-13,25-29,33,36,38 and 39 is/are rejected.
- 7) ☒ Claim(s) 26 and 27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. Applicant's Response to Office Action, received 12 January 2011, is acknowledged. Claims 13, 25, 27, 29, 33, 34, 38 and 39 have been amended. Claim 37 has been cancelled. New claims 40 and 41 have been added.
2. Claims 10-13, 25-29, 31-36 and 38-41 are pending and under consideration.

### **Objections/Rejections Moot or Withdrawn**

3. The objection to claim 33 is withdrawn in light of the amendment of the claim.
4. The rejection of claim 13 under 35 U.S.C. 101 is withdrawn in light of the amendment of the claim.
5. The rejection of claim 37 under 35 U.S.C. 112, second paragraph, as being indefinite for "having the same immunological characteristics", is moot in light of the cancellation of the claim.
6. The rejection of claims 29, 31, 32, 34, 35, 38 and 39 under 35 U.S.C. 112, second paragraph, as being indefinite for "having the same immunological characteristics", is withdrawn in light of the amendment of the claims.
7. The rejection of claims 27 and 28 under 35 U.S.C. 112, second paragraph, as being indefinite for "derived from", is withdrawn in light of the claim amendments.

### **Rejections Maintained**

8. The objection to claim 26 is maintained as no amendment of the claim has occurred.
9. The objection to claim 27 is maintained as no amendment of the claim has occurred to correct the improper dependency.

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10. The rejection of claims 10-13, 25-28, 33 and 36 under 35 U.S.C. 112, second paragraph, as being indefinite for "under stringent conditions", is maintained for the definition of "stringent conditions".

Applicant argues that the definition of stringent conditions is set forth on page 5, lines 13-25.

The examiner has considered applicant's argument, in light of the claim amendment, but does not find it persuasive as the definition recites that it "follows from" the formula of the cited reference, not that the definition "is" the formula.

11. The rejection of claims 25-29, 38 and 39 under 35 U.S.C. 112, first paragraph, scope of enablement for subunit vaccines of only one subunit, or of subunits 27 kD, 62 kD, 57 kD, 74 kD, 43 kD or 101 kD, is maintained.

Applicant argues that the Declaration under 37 CFR 1.132 of the inventor, Dr. Paul Vermeij, provides sufficient support for the scope of the instant claims.

The examiner has considered applicant's argument and Declaration, in light of the claim amendments, but does not find it persuasive at the present time without further clarification.

The specification recites utilizing "micro-Diluvac Forte" adjuvant. However, the Declaration recites utilizing "Diluvac Forte". Are these one and the same formulation or different formulations of adjuvant?

The specification recites that each antigen in said vaccine was at a concentration of 50 µg per ml. The Declaration does not recite the dosage concentration of the whole 75 kD protein utilized.

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Claims 25, 38 and 39 are drawn to a vaccine without an adjuvant, only a pharmaceutically acceptable carrier. The Declaration does not recite any vaccine without an adjuvant.

Claim 29 recites that the vaccine comprises antibodies against a protein consisting of SEQ ID NO:2. The Declaration contains no vaccines comprising only antibodies to SEQ ID NO:2.

### **Conclusion**

12. Claims 10-13, 25-29, 33, 36, 38 and 39 are finally rejected.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday-Thursday from 7:30 AM to 6:00 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Gary Nickol, at (571)272-0835.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

March 18, 2011